

REMARKS:

As an initial matter, Applicants appreciate the opportunity to discuss the present application with the Examiner in the interview on June 11, 2008. The present Amendment is filed based, at least in part, on the proposed amendments discussed during the interview and in further response to the Office Action mailed January 8, 2008. Claims 1, 40, and 151 have been canceled without prejudice, claims 92, 107, 113, 114, 149, 152, 154, 155, 181, 183, 184, 191, and 194 have been amended, and new claims 201-203 have been added. Therefore, claims 92, 95-99, 101, 105-110, 113, 114, 149, 150, 152, 154-158, and 181-203 are currently pending in the application with claims 187, 189, 196, and 198 withdrawn as directed to nonelected species.

The current claim amendments and new claims are fully supported by the original disclosure as filed, and do not present new matter. See, e.g., paragraphs [0061], [0111]-[0118], [0127], [0156], and [0160], and in FIGS. 12-15. No new matter has been introduced.

In the Office Action mailed on January 8, 2008, claims 1, 40, 92, 95, 96, 98, 99, and 101 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,773,390 (“the McDaniel reference”), claims 92, 97, 149-152, 154, 157, and 158 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,371,904 (“the Sirimanne et al. reference”), and claims 149-152 and 155-158 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 7,182,725 (“the Bonan et al. reference”). In addition, claims 105 and 106 were rejected under 35 U.S.C. § 103(a) as unpatentable over the McDaniel reference, claims 107-110 and 113 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Sirimanne reference in view of U.S. Patent No. 4,427,005 (“the Tener reference”), and claim 114 was rejected under 35 U.S.C. § 103(a) as unpatentable over the Sirimanne reference in view of the Tener reference and

further in view of the McDaniel reference. Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning first to the McDaniel reference, a radioactive source ribbon assembly 100 is disclosed that includes an inner assembly including a radioactive source 104, a core 106, a radioactive resistant sleeve 108 that encases the radioactive source 104 and core 106, and an outer jacket 102. Col. 3, lines 62-67. The assembly 100 also includes distal and proximal seals 114, 116 for sealing the inner assembly within the outer jacket 102. Col. 4, lines 2-5. In one embodiment, the assembly 300 includes a radiation resistant sleeve 308 sandwiched between the outer jacket 302 and the inner jacket 318. Col. 7, lines 53-60.

Turning to the present claims, claim 92 recites a system for delivering brachytherapy to a target tissue region of the breast that includes at least one elongate tubular member comprising proximal and distal ends and a lumen extending between an opening in the proximal end and the distal end, the tubular member configured to be delivered along a first axis within the target tissue region; one or more radiation sources receivable through the opening in the proximal end into the lumen of the tubular member after the distal end has been received within a target tissue region for delivering radiation therapy to the target tissue region along a second non-linear axis; and a support member extending along and substantially fixed to a target therapy portion of the tubular member such that the support member is adjacent the one or more radiation sources when the one or more radiation sources are disposed within the target therapy portion, the support member shaped to bias the target therapy portion for advancement through tissue in a straight

configuration and allow deployment to a curved configuration within the breast for delivery of radiation to the target tissue region.

First, the McDaniel reference does not disclose, teach, or suggest an elongate tubular member comprising a lumen extending between *an opening in the proximal end* and the distal end of the tubular member, nor one or more radiation sources receivable *through the opening* in the proximal end into the lumen of the tubular member *after the distal end has been received within a target tissue region*, as claimed. Instead, the McDaniel reference discloses a radioactive source 104 that is sealed within the outer jacket 102.

Second, the McDaniel reference fails to disclose, teach, or suggest a support member extending along and substantially fixed to a target therapy portion of the tubular member such that the support member is adjacent the one or more radiation sources when the one or more radiation sources are disposed within the target therapy portion. Even if the McDaniel core 106 could constitute a support member (which Applicants do not concede), the core 106 does not extend between proximal and distal ends of the outer jacket 102, but only extends partially from the proximal end of the outer jacket 102.

Finally, the McDaniel reference does not disclose, teach, or suggest a support member that is *shaped to bias the target therapy portion* for advancement through tissue in a straight configuration and allow deployment to a curved configuration within the breast for delivery of radiation to the target tissue region. Thus, even if the McDaniel radiation resistant sleeve 308 could constitute a support member (which Applicants also do not concede), the sleeve 308 does not bias the McDaniel assembly to allow straight advancement and curved deployment, but merely provides radiation resistance.

For each of these reasons, claim 92 and its dependent claims are neither anticipated by nor otherwise obvious over the McDaniel reference. For similar reasons, claims 92, 107, 181, 191, and 203 are also not anticipated by or obvious over the McDaniel reference.

Turning to the Sirimanne et al. reference discloses subcutaneous cavity marking devices, and fails to teach or suggest anything about brachytherapy. In particular, with reference to FIGS. 5A-5E, the Sirimanne et al. reference discloses radiopaque or echogenic wires that may be deployed into a tissue cavity. Col. 13, lines 54-57. The wire markers are not tubular members and do not receive radiation sources. As explained in Applicants' previous response, although the wires may be radiopaque, they do not constitute radiation sources, as required in the present claims. For this reason alone, none of the present claims are anticipated by or otherwise obvious over the Sirimanne et al. reference. In addition, the Sirimanne et al. reference does not teach or suggest an opening in a proximal end of a tubular member for receiving one or more radiation sources nor a support member, as presently claimed.

With respect to the Bonan et al. reference, a catheter 20 is disclosed that is intended to be inserted through a patient's vascular system into the patient's heart to ablate tissue at the AV node or other site. Col. 6, lines 38-44. With reference to FIGS. 9a and 9b, the Bonan et al. reference discloses that the catheter 62 may include steering wires, but fails to teach or suggest anything about support members.

First, the steering wires of the Bonan et al. reference cannot constitute a support member as presently claimed, because *the steering wires are not substantially fixed along a therapy delivery portion*. In direct contrast, the steering wires are necessarily movable along the distal

end of the catheter; otherwise, the steering wires could not be pulled to cause the distal end to bend.

In addition, the Bonan et al. steering wires are not *shaped to bias* the target therapy portion for advancement through tissue in a straight configuration and allow deployment to a curved configuration within the breast for delivery of radiation to the target tissue region, as recited in claim 92, nor are the steering wires a strip of material having a cross-section defining a width extending transversely relative to the first lumen and a height orthogonal to the width, the *height being smaller than the width*, as recited in claim 191. For these additional reasons, the present claims are neither anticipated by nor otherwise obvious over the Bonan et al. reference.

Applicants respectfully submit that the application is in condition for allowance in view of the forgoing amendments and remarks. Accordingly, reconsideration and allowance of the application is requested.

If there are any remaining issues that can be resolved by telephone, Applicants invite the Examiner to contact the undersigned at the number indicated below.

Respectfully submitted,
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Dated: June 17, 2008

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